

Express Mailing Label No. ER823448920US

US PATENT APPLICATION

Docket No. MLI-05 NPROV

UNITED STATES APPLICATION

of

DANIEL F. JUSTIN

and

BRENT E. STUCKER

for

Daniel F. Justin
REGISTERED PATENT AGENT
MedicineLodge, Inc.
180 South 600 West
Logan, UT 84321

LASER BASED METAL DEPOSITION (LBMD) OF IMPLANT STRUCTURES

LASER BASED METAL DEPOSITION OF IMPLANT STRUCTURES

CROSS-REFERENCE TO RELATED DOCUMENTS

[0001] This patent application claims benefit of pending prior U.S. Provisional Patent Application Serial No. 60/527,118, filed December 3, 2003 by Daniel F. Justin et al. for LASER ENGINEERED NET SHAPING OF IMPLANT STRUCTURES, (Attorney's Docket No. MLI-05), which patent application is hereby incorporated herein by reference.

FIELD OF THE INVENTION

[0002] The present invention relates to the formation of biocompatible materials onto a medical implant device, and more particularly to the use of laser based metal deposition of biocompatible materials onto a porous base material.

BACKGROUND OF THE INVENTION

[0003] The advancement of enhanced materials for the use of medical implants, such as joint prostheses have immensely improved the quality of life for many people over the past century. Devices such as artificial hips, knees, shoulders and other devices have allowed people who would otherwise have suffered from chronic pain and physical limitation to live active, comfortable lives. The development of such devices has confronted scientists and engineers with many technical challenges, such as in the area of materials science engineering wherein to achieve optimal implant performance

various biocompatible materials with different physical and mechanical properties are bonded to each other.

[0004] Materials used for such devices must not only be non-corrosive, but must also be sufficiently resilient (having high tensile and compressive strength), and hard (having sufficient wear resistance). Since a device such as an artificial joint must undergo a great number of cycles of wear during the lifetime of the host patient, such devices must also possess great fatigue properties.

[0005] Some medical implant devices such as artificial joints must bond in some way with the patient's natural bone. Early devices employed bonding polymers, commonly referred to as bone cement to bond the implant rigidly to the anatomic structure of bone. However, more recently such devices have been constructed of porous materials such as porous Titanium (Ti) and porous Tantalum (Ta). The bone of the host patient grows into the porous material creating a strong permanent mechanical bond without the use of bone cements. Consequently, such implants are more reliable and durable in the long term than those relying on bone cement for fixation.

[0006] Such implant devices are typically manufactured from a wrought alloy, forged alloy or a powder metal injection molded process. While this produces an implant device with bulk properties that are optimized for certain overall design criteria such as biocompatibility strength and modulus of elasticity, these properties may not be optimized for property requirements specific to certain portions of the implant, such as wear or bone ingrowth characteristics.

[0007] For instance, while the use of porous materials such as porous Ti provides crucial and beneficial bonding properties, such materials may not have optimal

properties in other areas. For example, porous materials, may not be as hard as some other biocompatible materials and therefore may not have acceptable wear properties. However, because of the overriding importance of strong permanent bonding with the host patient bone, such porous materials have continued to be used in spite of less than optimal wear properties.

[0008] In order to enhance the wear properties of a device such as an artificial joint, prior art devices have been constructed in more than one piece. A first portion of the joint implant, that which will bond to the bone, has typically been constructed of a porous material such as porous titanium, and a second piece, such as the bearing surface of the joint, has been constructed of a much harder, more wear resistant material such as alloys of cobalt and chrome (Co-Cr). The first and second pieces are then bonded together in an attempt to obtain the benefits of both materials. One challenge to using such a technique is that of achieving a sufficiently strong, permanent bond between the first and second portions, without the use of adhesives that may be biologically incompatible or may fail under the stresses imposed by the body of the patient. Attempting to weld such materials together can cause the non-porous material to flow into the porous material, destroying the porosity of the porous material and degrading the ability of the device to bond with the patient's bone. In addition, such materials, being dissimilar metals, often experience galvanic corrosion when bonded together in such a manner.

[0009] Therefore, there remains need for a device (and method for making the same) such as an artificial joint which can take advantage of the properties of a first material, such as the porosity of porous Ta or Ti, and also take advantage of the

properties of a second material, such as the hardness of a material like Co-Cr, for use in a bearing environment such as a ball or socket of a joint. Such a device would preferably not exhibit any delamination between the two materials and would not experience any galvanic corrosion. Such a device would also preferably not diminish the porosity of the porous material due to the flow of the other material thereinto.

Daniel F. Justin
REGISTERED PATENT AGENT
MedicineLodge, Inc.
180 South 600 West
Logan, UT 84321

SUMMARY OF INVENTION

[0010] The present invention provides a method for constructing a medical implant such as a hip prosthesis, having a bulk portion constructed of a porous material which can fuse with a host patient's bone structure, and which also has a hard, wear resistant material only at portions of the device where such properties are desired. According to the invention, a Laser based metal deposition (LBMD) layer of relatively dense hard material, can be applied to a porous material.

[0011] The relatively hard, wear resistant biocompatible material can be for example an alloy of cobalt and chrome alloy, whereas the porous material could be a biocompatible material conducive to bony tissue ingrowth when formed in a porous structure such as porous Titanium, Ti6Al4V, Ti6Al4V ELI, Titanium-Nickel alloys, Tantalum, Tantalum alloys, and porous structures made from other materials that have an exposed surface made from biocompatible materials.

[0012] According to the LBMD material application of the present invention, the applied material can be applied as, for example, powdered metal, as a wire or as a foil. The applied material is then melted by a high-energy laser immediately upon or soon after application. The use of a laser to heat the applied material advantageously allows the heating to be very localized, thereby minimizing any adverse effects of such heat on the underlying material.

[0013] In addition, the extremely localized heating of the laser in conjunction with the heat sinking properties of the underlying material leads to very rapid subsequent cooling, resulting in a beneficial small grain structure as well as allows the addition of carbon interspersions when conducted in a carbon-rich environment or with

powered or alloyed carbon added to the deposition material, both of which provide increased hardness to the deposited material.

[0014] Furthermore, since the LBMD deposited material is heated and cooled so quickly and locally, the applied material tends not to flow excessively into the porous material, thereby maintaining the desirable porous properties of the porous bulk portion of the device and a relatively small bonding zone between the porous material and the LBMD deposited material. This allows for a thin layer of LBMD deposited material to be deposited onto the porous material. Because this layer of deposited material is thin, implants can be fabricated that are optimized in size to limit the amount of bone that must be removed to facilitate the bulk of the implant. For example, a 5 millimeter thick sheet-like implant with a 3 millimeter thick porous bone ingrowth underside, a 0.5 millimeter bonding zone, and 1.5 millimeter bearing surface made from a first layer of Titanium and a second layer of Cobalt-Chrome can be placed as bearing pads on the proximal tibial plateau as a tibial hemiplasty implant in the knee. This construct of the 5 millimeter thick implant is significantly bone conserving compared to traditional 9 millimeter to 20 millimeter thick tibial implants that are currently used to resurface the proximal tibia of the knee.

[0015] In another aspect of the invention, a relatively hard material such as Co-Cr can be applied to the surface of a porous base such as porous Tantalum, and the Co-Cr surface used to bond to a Co-Cr bulk portion of the device. This overcomes the problems that have previously been experienced, when trying to bond a material such as Co-Cr to another material such as porous Tantalum. A corrosion barrier, such as a layer of Ti may be provided between the porous Tantalum and the Co-Cr.

[0016] The present invention provides a manufacturing method for producing an implant made from traditional or novel implant metals with layers of material having differing densities and structures.

[0017] The present invention provides a surface material deposition process that allows for a gradient of materials with varying selective properties to be deposited on the bulk implant material. After the base structure is formed, additional material is added to the base structure using the laser based metal deposition (LBMD) process.

[0018] The implant is formed in the approximate final shape from a common or novel orthopedic alloy such as Co-Cr alloys, titanium alloys, stainless steel alloys, or base pure metal such as tantalum, titanium or platinum. Because the basic structure of the implant is formed by conventional manufacturing means out of implant grade materials, the majority of the cost of the manufacturing is similar to existing implants.

[0019] Applicable implant shapes that can benefit from LBMD deposition of harder materials onto the base material include knee, shoulder, hip, finger, spine, top, foot, elbow, wrist, dental, jaw, and ankle prosthesis, just to name a few.

[0020] Besides improving bearing properties of implants, the LBMD process can be used to increase the bone ingrowth properties of implant surfaces. This can be done by either depositing a hard material onto a porous base material or depositing a porous material onto a hard material.

[0021] In the case of adding a hard material to a base material, a monoblock of a porous structure of an implant material is the base material. A closely packed fine grain structure of an implant material is then added to the base material by laser based

metal deposition (LBMD) methods. The closely packed grain structure would result in improved wear properties.

[0022] The majority of the bulk of the implant can be manufactured by conventional methods. The hardened surface may then be added by LBMD deposition. Unlike structures that are completely made by methods such as LBMD, this method would allow the majority of the structure to be built by conventional methods with only thin layers of hard material added to the structure. Accordingly, cost savings can be achieved.

[0023] LBMD allows for a highly focused laser beam of energy to melt a very small amount of powder over a short period of time. Because the large bulk material acts as a heat sink, this process results in a rapidly cooled LBMD deposited material. Rapid cooling of materials such as metals results in a finer grain structure, which results in increased hardness. In addition, in a carbon rich environment, carbides form resulting in an even harder material. Since the hardness of a material is typically directly related to wear resistance, materials having high hardness become very attractive for use on bearing surfaces such as those on knee, hip, wrist and elbow joints as well as myriad other implant devices.

[0024] Using the material deposition process of the present invention, like materials can be deposited onto like materials such as Co-Cr alloys LBMD deposited on Co-Cr wrought materials. However, dissimilar materials may also be deposited, such as titanium alloys deposited on Co-Cr alloys, or Co-Cr alloys can be deposited on titanium and its alloys.

[0025] Other aspects and advantages of the present invention will become apparent from the following detailed description, which, when taken in conjunction with the drawings, illustrate by way of example the principles of the invention.

Daniel F. Justin
REGISTERED PATENT AGENT
MedicineLodge, Inc.
180 South 600 West
Logan, UT 84321

BREIF DESCRIPTION OF THE DRAWINGS

[0026] For a fuller understanding of the nature and advantages of this invention, as well as the preferred mode of use, reference should be made to the following detailed description read in conjunction with the accompanying drawings.

[0027] Figure 1 shows an example of the present invention employed in a hip prosthesis;

[0028] Figure 2 is a view taken from circle 2 of Figure 1, showing the a cross section of the surface of the hip prosthesis of Figure 1;

[0029] Figure 3A illustrates the deposition of a first material using laser based metal deposition (LBMD);

[0030] Figure 3B illustrates the deposition of a second material on the first material of Figure 3A using laser based metal deposition (LBMD);

[0031] Figure 3C is a micrograph at 5X magnification that shows three layers of Co-Cr alloy deposited by the LBMD process on a bulk material of wrought Co-Cr;

[0032] Figure 3D is a micrograph at 5X magnification of nine layers of Co-Cr alloy deposited by LBMD on a bulk material of wrought Co-Cr;

[0033] Figure 3E is a micrograph at 50X magnification showing the bulk wrought Co-Cr alloy;

[0034] Figure 3F is a micrograph at 50X magnification showing the LBMD deposited Co-Cr alloy, particularly showing the finer grain structure associated with a rapidly cooled LBMD deposited material;

[0035] Figure 4 illustrates an alternate application of the present invention;

[0036] Figure 5 shows various implants that could have improved bone ingrowths or bearing properties if processed by LBMD;

[0037] Figure 6 is a partial cross sectional view of the toe implant of Figure 5 taken along line 6-6 of Figure 5;

[0038] Figure 7 is a partial cross sectional view of the dental implant of Figure 5 taken along line 7-7 of Figure 5;

[0039] Figure 8 is a partial cross sectional view of one articulating implant of Figure 5 taken along line 8-8 of Figure 5.;

[0040] Figure 9 is a partial cross sectional view of the thumb implant 508 of Figure 5 taken along line 9-9 of Figure 5; and

[0041] Figure 10 is an exploded view the knee implant of Figure 5 and a multi-layer structure coupling thereto.

DETAILED DESCRIPTION OF THE PERFERED EMBODIMENTS

[0042] The following description is the best embodiment presently contemplated for carrying out this invention. This description is made for the purpose of illustrating the general principles of this invention and is not meant to limit the inventive concepts claimed herein.

[0043] With reference to Figure, **1**, a preferred embodiment of the present invention will be described in terms of a hip prosthesis (hip) **100** for implanting in the body of a patient. However, this is only by way of example, and it should be understood the present invention can practiced on many other medically implanted devices, including without limitation, knee, shoulder and elbow prostheses, as well as many other devices. Note Figure **5**, discussed below.

[0044] The hip prostheses **100** must be constructed completely of biocompatible materials in order to ensure acceptance of the prostheses by the patient's body. A biocompatible material is one that will not cause an adverse reaction with a host patient, and that will not corrode when exposed to human tissue and fluids within the host patient. The hip **100** includes a base portion **102**, which may include a shank **104** and a ball **106**, and that is constructed predominantly or completely of a porous material such as porous Ti or Ta (or alloys thereof). Constructing the shank **104** of a porous material such as Ti or Ta advantageously promotes bone growth into the porous material and strong fusion therewith. This provides a strong, permanent, resilient bond with the bone of the host patient without the need for adhesives. As discussed above, the use of adhesives to bond the hip **100** to the bone of the host patient would not only provide a

somewhat unreliable bond, but could also lead to adverse reactions with the host patient.

[0045] As also mentioned above, the base 102 is constructed either completely or predominantly of a porous material, such as a porous matrix of Ta or Ta alloy, Ti or Ti alloy, for example Ti-6Al-4V, Ti-Ni, Ti6Al4V ELI, Titanium-Nickel alloys, and porous structures made from other materials that have an exposed surface made from biocompatible materials. The base 102 can be formed by methods such as casting, machining or forging.

[0046] A preferred material for the base 102 is porous tantalum. One such porous tantalum is sold under the brand name HEDROCEL® by IMPLEX® Corporation, 80 Commerce Drive, Allendale, New Jersey 07401.

[0047] The preferred porous tantalum material such as HEDROCEL® has an open cell, tantalum metal structure that has the appearance of cancellous bone, and that can be formed or machined into complex shapes. It is distinguished from current porous materials by its uniformity and structural continuity as well as by its strength, toughness, and resistance to fatigue failure.

[0048] The tantalum metal structure consists of interconnecting pores, resulting in a construct that is >60% porous, and ideally >75% porous. In addition, the tantalum material preferably has flexural modulus properties that are similar to those of human bone. For articulating joint replacement devices, compression molded polyethylene can be infused into the tantalum structure, creating a bond as strong as the polyethylene itself. In addition, the titanium structure can be fabricated into products without the need for solid metal support.

[0049] The preferred porous tantalum metal (e.g., HEDROCEL®) has a similar cellular geometric appearance to bone graft, and also offers many beneficial attributes. The porous structure is preferably a uniform and homogeneous biomaterial, having load carrying capabilities that are engineered to the orthopedic application. Bone graft, whether harvested from the patient or taken from the bone bank, has varying, often unknown degrees of mechanical properties and overall quality. Similarly, the bone must incorporate into the surrounding bone for long-term clinical success. If the bone dies or does not generate new bone, the fatigue characteristics will be poor and can lead to collapse, loosening, pain, and re-operation. The preferred tantalum material is highly fatigue resistant and maintains its strength for the duration of clinical usage. The mechanical properties should not degrade with time. Since the stiffness properties of the preferred tantalum material are similar to bone, the load pattern to the surrounding bone should be maintained without a compromise of quality.

[0050] The preferred tantalum material has a volumetric porosity greater than traditional prosthetic materials and bone fixation surface coatings. This high porosity allows a more normal restoration of the bone in contact with the porous material, unlike the bone density change phenomenon seen with minimally porous or non-porous implant materials. The solid metals used in current implants are at least ten times stiffer than bone, whereas the tantalum material preferably has a stiffness similar to that of bone.

[0051] Initial stability is equally important and is necessary for proper bone in-growth. The tantalum material will preferably have high frictional characteristics when

contacting bone. In the early post-operative period, these frictional and structural properties allow the implant device to remain very stable.

[0052] For soft tissue applications, the properties of porous tantalum have an important role. Similar to bone, the overwhelming volumetric porosity allows fast penetration of precursor cells and relatively fast formation of soft tissue fibral strands and blood supply. Unlike solid metal screws, washers or synthetic sutures, porous tantalum achieves the primary mode of tissue attachment to the implant device while the tissues heal at their own variable pace. The struts of the porous tantalum material interlock with the tissue, offering immediate, secure and functional mechanical attachment. This allows for the necessary healing and reproducible tissue incorporation into the porous matrix. The use of a porous tantalum soft tissue anchoring device may therefore result in both soft tissue in-growth and bone in-growth for long-term fixation.

[0053] One method for forming a base **102** of porous tantalum is described in U.S. Patent No. 5,282,861 to Kaplan, issued Feb. 1, 1994, and which is herein incorporated by reference. According to the method, the metal, such as tantalum, is deposited on a carbon foam substrate. A reaction chamber encloses a chlorination chamber and a hot wall furnace. A resistance heater surrounds the chlorination chamber and an induction heating coil surrounds the reaction chamber to heat the hot wall furnace. Tantalum metal is located within the chlorination chamber and a carbon foam substrate is positioned within the hot wall furnace. Chlorine gas is injected into the chlorination chamber to react with the tantalum to form tantalum chloride. The tantalum chloride mixes with hydrogen injected into the chamber and then passes through an opening in the hot wall furnace. The mixture is heated within the hot wall

furnace of a temperature of approximately 1100° C to produce the following reacting surface $\text{TaCl}_5 + 5/2 \text{H}_2 \rightarrow \text{Ta} + 5 \text{HCl}$. The surface reaction deposits the tantalum on the carbon foam substrate to produce a uniform thin film over the individual ligaments of the substrate. The hydrogen chloride is then exhausted.

[0054] It should be appreciated that although the substrate has been indicated to be carbon, other carbaceous materials, such as graphite, may be used. In addition, other open cell materials, such as high temperature ceramics, may also be used. Also, other layers may be deposited on the substrate, such as intermediate layers to provide additional strength. Other aspects of the invention could be the incorporation of a core of solid material, such as tantalum or niobium or alloys of each, with the porous substrate fitted around the solid core and with the subsequent deposition of metal not only covering the substrate but also locking the porous substrate to the solid core.

[0055] The base **102** may also comprise porous tantalum formed on a substrate material. A method for forming the base **102** of porous tantalum on a substrate material is disclosed in U.S. Patent No. 6,063,442 to Cohen et al, issued May 16, 2000, and which is herein incorporated by reference.

[0056] In another method of forming the base **102**, spherical beads or particles (not shown) of Ti or Ti alloy can be charged into a mold or form. The beads are preferably of relatively uniform shape. It is within the skill of one in the art to select a bead size range to result in a desired porous matrix with the desired pore size. The beads can then be exposed to high temperature in a Hot Isostatic Pressing (HIP) process to sinter the beads into the desired solid matrix form.

[0057] The HIP process is carried out in an oven that includes an airlock. The base **102** is prepared as described above and placed within the oven, which is then evacuated and charged with an inert (e.g., argon) atmosphere. The oven is heated to the desired temperature while the atmosphere therein is pressurized to the desired pressure. The HIP process applies an isostatic pressure through the inert gas (e.g., argon). By applying sufficient pressure during the heating step, the beads are fused together at temperature below that which would adversely affect the microstructure of the material.

[0058] With continued reference to Figure **1**, the hip **100** also includes a ball **106** which has a relatively dense, hard and wear resistant outer surface region **108** due to the unique processing and material described hereinbelow. The ball **106** fits within a prosthetic acetabular socket cup (not shown) and the outer surface region **108** of the ball **106** forms a bearing surface with the inner surface of the socket cup. While the porous material, such as porous Ti or Ta making up the base **102** (and ball **106**) has advantageous bone fusion properties, it would not have optimal wear properties for surfaces such as the bearing surface of the ball **106**.

[0059] With reference to Figure **2**, the outer surface region **108** of the ball **106** of the hip **100** can be seen in more detail. The outer surface region **108** includes a corrosion barrier layer **110** over which a hard dense outer material **112** such as Co-Cr is formed.

[0060] The outer surface region **108**, including the corrosion barrier layer **110** and the outer material **112**, can be constructed as laser based metal deposition (LBMD) layers. An example of a LBMD process is Laser Engineered Net Shaping (LENSTM), Sandia Corporation of Albuquerque, New Mexico, is described in U.S. Patent No.

6,046,426 to Jeantette, et al., issued on April 4, 2000, and which is incorporated herein by reference. Initially, a layer is deposited directly on the ball **106**. Thereafter, subsequent layers can be deposited on previous layers in a controlled manner until a desired surface shape is formed. The material can be deposited for example as a powdered metal emitted from one or more nozzles. Alternatively, the material could be provided as a wire or as a foil, held in proximity to the base and heated with the laser.

[0061] Figures **3A-B** illustrate the construction of the outer surface region **108** of the ball **106** according to a preferred LBMD process. As shown, the corrosion barrier layer **110** is formed first by depositing a layer of corrosion-resistant material **118** such as Ti or Ti alloy onto the ball **106**, and immediately heating the material with a high power laser **113**. Then the outer layer **112** is formed on the corrosion barrier layer **110**, again by deposition and laser heating. More detail about a preferred process is provided below.

[0062] As shown in Figure **3A**, a powdered material feeder (not shown) provides a uniform and continuous flow of a measured amount of powdered material **118** to the delivery system, or nozzle **114**. The delivery system directs the powdered material **118** toward the ball **106** and directs the powdered material **118** to flow in a converging, conical pattern whereby the apex of such converging, conical pattern intersects the minimum diameter of a focused laser beam (i.e. focus or focal plane) produced by a laser **113** such as an Nd YAG laser, all of which is in close proximity to the surface of the base **102**. This generates a melt zone **118**, wherein a substantial portion of the powdered material **118** melts and is deposited on the surface of the ball **106**. Those skilled in the art will appreciate that such powdered material can melt either in flight or

upon injection into a molten puddle of powdered material. By causing the ball 106 to move relative to the delivery system or by moving the delivery system relative to the ball 106, layers of molten deposited material can be deposited to form a net-shaped surface.

[0063] The deposited corrosion barrier layer 110 may be deposited as a single layer, or as multiple layers applied by successive passes of LBMD deposition. For instance, laminates of corrosion-resistant material (e.g., Ti and/or Ti alloys, etc.) can be formed to create the corrosion barrier layer 110.

[0064] Referring to Figure 3B, the layer of outer material 112 is formed on the corrosion barrier layer 110 by a LBMD process as set forth above, this time using biocompatible material 120 that has a high wear resistance, such as Co-Cr alloy. Again, laminates of high wear resistance material can be formed. Figure 3C is a micrograph at 5X magnification that shows three layers of Co-Cr alloy 140 deposited by the LBMD process on a bulk material of wrought Co-Cr 142. Figure 3D is a micrograph at 5X magnification of nine layers of Co-Cr alloy deposited by LBMD on a bulk material of wrought Co-Cr. Figure 3E is a micrograph at 50X magnification showing the bulk wrought Co-Cr alloy. Figure 3F is a micrograph at 50X magnification showing the LBMD deposited Co-Cr alloy, particularly showing the finer grain structure associated with a rapidly cooled LBMD deposited material.

[0065] Either of the layers 110, 112 can also be formed to have a gradient of material qualities; for example the outer material 112 could be formed to become progressively harder toward the outer surface of the outer material 112.

[0066] Additional layers can also be added above, below, or between the corrosion barrier layer 110 and layer of outer material 112 per the desires of the manufacturer or need in the industry.

[0067] The LBMD deposition process is preferably performed in a controlled atmosphere chamber (not shown) which contains an inert gas to inhibit the formation of surface oxide in the deposition area. This reduces the amount of laser energy needed to achieve full melting of the powder. Although deposition can be performed outside the controlled atmosphere chamber, the inert atmosphere will promote full density in the deposited structure and ultimately lead to improved strength of the applied surface material.

[0068] It should be appreciated that the laser heats the LBMD deposited material in a very localized manner and for a very short duration. Because of this the heat does not appreciably heat the base material, and thus the heat does not adversely affect the structure of the base material. Furthermore, the large heat sink of the ball 106 combined with the very small area of localized heating causes the heated deposited material to very rapidly cool. This results in a finer grain structure than would occur with a slower cooling, and also results in carbide interspersions when conducted in a carbon-rich environment. As those skilled in the art will appreciate, fine grain structure and the presence of carbide interspersions both contribute to improved hardness and therefore improved wear properties.

[0069] In addition, because of the rapid rate of heating and cooling, the applied material does not tend to excessively flow into the porous material, thereby maintaining the desirable porous properties of the porous bulk portion of the device and a relatively

small bonding zone between the porous material and the LBMD deposited material.

This allows for a thin layer of LBMD deposited material to be deposited onto the porous material. Because this layer of deposited material is thin, implants can be fabricated that are optimized in size to limit the amount of bone that must be removed to facilitate the bulk of the implant. For example, a 5 millimeter thick sheet-like implant with a 3 millimeter thick porous bone ingrowth underside, a 0.5 millimeter bonding zone, and 1.5 millimeter bearing surface made from a first layer of Titanium and a second layer of Cobalt-Chrome can be placed as bearing pads on the proximal tibial plateau as a tibial hemiplasty implant in the knee. This construct of the 5 millimeter thick implant is significantly bone-conserving compared to traditional 9 millimeter to 20 millimeter thick tibial implants that are currently used to resurface the proximal tibia of the knee.

[0070] As mentioned above, the deposited layers may be deposited as multiple layers applied by successive passes of LBMD deposition. It should be pointed out the heat used to apply each layer and/or the material composition can be adjusted with each pass to achieve a gradient of material properties if desired. For example, the layer could be applied so that the applied layers are progressively harder toward the surface of the structure.

[0071] Another preferred embodiment includes a multi-layer "sandwich" of Co-Cr alloy (outer material 112) on titanium (corrosion barrier layer 110) on a porous tantalum or titanium base material. LBMD is used to directly deposit titanium onto porous tantalum or titanium and Co-Cr onto the previously deposited titanium.

Illustrative dimensions of such an embodiment follow. The thickness of the porous

tantalum can be about 0.040 to 1.000 inches, the thickness of the mixed titanium and tantalum layer can be between about 0.010 and 0.050 inch. The thickness of the titanium layer can be between about 0.010 and 0.050 inch. The thickness of the mixed titanium and Co-Cr layer can be about 0.001 to 0.010 inch. The thickness of the Co-Cr layer can be about 0.010 to 0.500 inch. Thus, a sandwich of tantalum, titanium, Co-Cr could range from about 0.071 inches to 1.61 inches. Of course these dimensions are provided by way of example, and will vary depending on the type and use of the implant device.

[0072] According to another preferred embodiment, multi-layer structures such as that described in the preceding paragraph can be formed for coupling to another device such as a commercially available implant. For instance, such multi-layer structures can be fusion or diffusion bonded to implants that are made by traditional methods. Thus, for example, the Co-Cr surface of a 0.200 inch three layer structure could be diffusion bonded to a hip or knee implant, as shown in Figure 10. The porous surface would then advantageously be available for coupling to bone of a host patient.

[0073] In fusion bonding, the substrates are first forced into intimate contact by applying a high contact force. The substrates are then placed in a furnace and annealed at high temperature, after which a solid bond is formed between the substrates. In diffusion bonding, the substrates are forced into intimate contact under high contact force, and heated at a temperature below the melting point of the substrate materials. Fusion bonds involve the complete melting and mixing of both metals. Diffusion bonding can be viewed as a form of fusion bonding but with much less melting and mixing of both metals.

[0074] With reference to Figure 4, according to another embodiment of the invention, the present invention could be used to provide improved bonding of a first portion **400** of a prosthetic device **402** to a second portion **404** of the device **402**. For example, the first portion **400** might be constructed primarily of hard, dense material such as Co-Cr, while the second portion **404** might be constructed of a porous material such as porous Ti. Heretofore, bonding of porous Ti with a material such as Co-Cr has achieved poor results. In addition, bonding porous Ti with Co-Cr, resulted in galvanic corrosion across the two dissimilar metals.

[0075] According to the present invention, a corrosion barrier layer **406** can be deposited onto the first portion **400** by laser based metal deposition (LBMD). Thereafter, a layer of Co-Cr **408** can be deposited onto the corrosion barrier layer, again by LBMD deposition. Co-Cr can be bonded very well with Co-Cr. Therefore, the LBMD deposited Co-Cr outer surface **408** of the second portion **404** can achieve excellent bonding with the Co-Cr of the first portion **400** without any corrosion problems.

[0076] Figure 5 illustrates by way of example and not limitation, various other possible devices in which the present invention might be embodied. Devices shown in Figure 5 include a TMJ joint **500** in situ, an implant for the great toe **502** (also generally representative of knee, wrist and spinal implants), a dental implant **504** in situ, articulating finger implants **506**, thumb implants **508**, a wrist implant **510** in situ, dental implants **512** in situ, a dental implant **514** in situ, a knee implant **516**, and a shoulder implant **518** in situ. More detail about each of these implants is set forth below.

[0077] Figure 6 is a partial cross sectional view of the toe implant 502 of Figure 5 taken along line 6-6 of Figure 5. As shown, the implant 502 has a shank 600 and a knuckle portion 602 formed from a unitary body of porous material such as tantalum. The porous shank 600 remains exposed for fusion with bone. However, because the knuckle portion 602 is designed to engage a corresponding knuckle of bone, metal or ceramic, the knuckle portion 602 has a smooth outer surface that must be resistant to wear. Using the LBMD process described above, a corrosion resistant layer 604 of corrosion-resistant material (e.g., Ti) is formed on at least a portion of the knuckle portion. An outer layer 606 of a wear resistant material (e.g., Co-Cr alloy) is formed over the corrosion resistant layer 604.

[0078] Figure 7 is a partial cross sectional view of the dental implant 504 of Figure 5 taken along line 7-7 of Figure 5. As shown, the implant 504 has a shank 700 and a tooth coupling portion 702 formed from a unitary body of porous material such as tantalum. The porous shank 700 remains exposed for fusion with the jaw bone. However, because the tooth coupling portion 702 is designed to engage an artificial tooth, the tooth coupling portion 702 must be resistant to wear created by the stresses of chewing food. Using the LBMD process described above, a corrosion resistant layer 704 of corrosion-resistant material (e.g., Ti) is formed on at least a portion of the tooth coupling portion 702. An outer layer 706 of a wear resistant material (e.g., Co-Cr alloy) is formed over the corrosion resistant layer 704.

[0079] Note that an implant similar to the implant 504 of Figure 7 can be used with the TMJ joint 500 of Figure 5 to secure the TMJ joint to the jaw and cranium of the host patient. In that case, the implant would be formed of a unitary body of porous

material for fusion with bone, the portion of the implant engaging the hinged members would have the corrosion resistant layer and durable outer layer formed thereon by the LBMD process. The durable outer layer would resist wear between the implant and the hinged member caused by the stresses of chewing.

[0080] Figure 8 is a partial cross sectional view of one articulating implant 506 of Figure 5 taken along line 8-8 of Figure 5. As shown, the implant 506 has a shank 800 and a ball portion 802 formed from a unitary body of porous material such as tantalum. The porous shank 800 remains exposed for fusion with the finger bone. However, because the ball portion 802 is designed to engage a corresponding metal socket, the ball portion 802 must be resistant to wear. Using the LBMD process described above, a corrosion resistant layer 804 of corrosion-resistant material (e.g., Ti) is formed on at least a portion of the ball portion 802. An outer layer 806 of a wear resistant material (e.g., Co-Cr alloy) is formed over the corrosion resistant layer 804.

[0081] Figure 9 is a partial cross sectional view of the thumb implant 508 of Figure 5 taken along line 9-9 of Figure 5. As shown, the implant 508 has a shank 900 and a knuckle portion 902. Here, the shank 900 is formed of hydroxy apatite. The knuckle portion 902 is made of metal coupled to the shank 900. The porous shank 900 remains exposed for fusion with bone. However, because the knuckle portion 902 is designed to engage a corresponding knuckle 903, the knuckle portion 902 has a smooth outer surface that must be resistant to wear. Using the LBMD process described above, a corrosion resistant layer 904 of corrosion-resistant material (e.g., Ti) is formed on at least a portion of the knuckle portion. An outer layer 906 of a wear resistant material (e.g., Co-Cr alloy) is formed over the corrosion resistant layer 904.

[0082] Figure 10 depicts the knee implant 516 of Figure 5. In this embodiment, a multi-layer structure 1000 is independently formed for insertion in the depression 1002 of the implant 516. The multi-layer structure 1000 is formed of a first layer 1004 of Co-Cr, a middle layer 1006 of corrosion resistant material (e.g., Ti), and an outer layer 1008 of a porous material (e.g., Ta). The multi-layer structure can be fusion or diffusion bonded to the implant 516 that has been made by traditional methods. For example, the Co-Cr surface 1004 of a 0.200 inch three layer structure can be diffusion bonded to the implant 516. The porous surface of the outer layer 1008 is then advantageously available for coupling to bone of a host patient. A description of how to form such multi-layer structures and how to couple them to implants has been provided above.

[0083] While the present invention has been disclosed in its preferred form, the specific embodiments thereof as disclosed and illustrated herein are not to be considered in a limiting sense, as numerous variations are possible. The invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. No single feature, function, element or property of the disclosed embodiments is essential. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. The following claims define certain combinations and subcombinations that are regarded as novel and non-obvious. Other combinations and subcombinations of features, functions, elements and/or properties may be claimed through amendment of the present claims or presentation of new claims in this or related applications. Such claims, whether they are broader, narrower or equal in scope to the original claims, are also regarded as

included within the subject matter of applicant's invention. All changes that come within the meaning and range of equivalency of the claims are to be embraced within their scope. For example, for purposes of simplicity the invention was described in terms of a hip prosthesis. However this was only by way of example, and as those skilled in the art will appreciate the present invention could be practiced in many other applications. Other variation and embodiments falling within the scope of the invention will, no doubt be apparent to those skilled in the art. Thus, the breadth and scope of a preferred embodiment should not be limited by any of the above-described exemplary embodiments, but should be defined only in accordance with the following claims and their equivalents.

Daniel F. Justin
REGISTERED PATENT AGENT
MedicineLodge, Inc.
180 South 600 West
Logan, UT 84321